U.S. Senate
Republican Policy
Committee

Conference Report Highlights

Jon Kyl, Chairman

November 22, 2003

Highlights of the Conference Report to Accompany H.R. 1, The Medicare Prescription Drug, Improvement, and Modernization Act of 2003

The Conference Report, H. Rept. 108-391, was filed on November 21, 2003.

NOTEWORTHY

- Based on a preliminary review, the Congressional Budget Office (CBO) estimates that the legislation would increase direct spending by $395 billion over the 2004-2013 period. It also would lead to an increase in federal revenues totaling $500 million over the same 10-year period.
- The Conference Report establishes a voluntary prescription drug benefit under the Medicare program. It also creates a new "Medicare Advantage" program, providing seniors with a menu of health plan choices, including preferred provider organization (PPO) and health maintenance organization (HMO) options.
- The Conference Report provides financial assistance to approximately one-third of Medicare beneficiaries who meet low-income thresholds.
- Employment-based retiree health plans will receive up to 28 percent in federal assistance for beneficiary drug costs between $250 and $5,000. The subsidy for retiree prescription drug coverage is excludable from taxation.
- The legislation contains new Medicaid and Medicare payments for health care providers, including, but not limited to, hospitals, physicians, rural health clinics, and ambulances.

- The Conference Report also includes several beneficiary program changes, such as increasing the Part B deductible and applying an income test for the Part B premium. In addition, it provides new preventative health benefits, including an initial physical exam and screening tests for diabetes and cardiovascular disease.
- The Conference Report contains revisions to the Hatch-Waxman law, enabling generic drugs to come to the market sooner.

- The Conference Report includes legislative language, based on S. 1, that allows the importation of prescription drugs from Canada only as long as the Secretary certifies that each prescription is safe and effective. In addition, the Secretary is required to conduct a study to address other potential safety concerns as well as analyze the impact of foreign pharmaceutical price controls and the role of trade negotiations.

- The Conference Report creates tax-free savings accounts, known as Health Savings Accounts (HSAs), to be used for qualified medical expenses. (These accounts formerly were known as medical savings accounts.)

- The legislation contains a cost-containment mechanism to provide transparency in accounting and congressional review of the Medicare program if general revenue contributions exceed 45% of program spending.

- The House passed the Conference Report on November 22, by a vote of 220 to 215.

HIGHLIGHTS

Title I - Medicare Prescription Drug Benefit

Starting in April 2004, all Medicare beneficiaries would have access to a discount card for prescription drug purchases. Drug discount cards would be available for 2 years. Projected savings from the card for consumers would range between 15 percent and 25 percent. Low-income beneficiaries would receive a $600 subsidy applied to the card but would still be required to pay a coinsurance amount between 5 percent and 10 percent for each prescription drug. Sponsors for such cards could include Pharmacy Benefit Managers (PBMs), wholesalers, retail pharmacies, insurers, or Medicare + Choice plans. However, sponsors would be prohibited from offering mail-order-only programs.

Effective January 1, 2006, a new optional benefit would be established under Medicare Part D. Coverage includes prescription drugs, biological products, insulin, and certain vaccines. Beneficiaries could

choose either "standard coverage" offered by a Prescription Drug Plan (PDP) or as part of a Medicare Advantage plan. Beneficiaries may also receive drug coverage through an employment-based retiree plan. The standard coverage would include the following cost-sharing amounts, indexed for inflation:

	Senior Cost
Monthly Premium	$35 (average)
Deductible	$250
Coinsurance	25% beneficiary cost-sharing up to $2,250 of drug expenses
Catastrophic	5% beneficiary cost-sharing, or $2 copays for generic drugs and $5 copays for brand-name drugs applied to all drug spending once the beneficiary has spent $3,600 out of pocket.

Out-of-pocket expenses are defined as those paid by the individual, as well as State Pharmaceutical Assistance Programs (SPAPs) paid on behalf of a low-income individual. Costs reimbursed by other supplemental insurance plans will not be included in such calculations.

Substantial assistance is provided to low-income beneficiaries. For instance, those beneficiaries that are dually eligible for both Medicaid and Medicare would no longer receive prescription drug assistance through their state Medicaid programs as previously proposed under S. 1. Instead, they now would have access to the Medicare program for such benefits. Federal rules would apply throughout the benefit. The Conference Report, in addition, modified the House provision to phase down state contributions for Medicare dual eligible drug costs. This would be implemented over 10 years, phasing down from 100 percent to 75 percent of the state contribution. For those dual eligibles with incomes below 100 percent of the federal poverty level ($9,670 for singles and $13,051 for couples), they would have to pay $1 for every generic drug prescribed and $3 for every brand-name drug prescribed.

For all remaining low-income beneficiaries, they would receive assistance at varying levels. Assistance is based on the following categories:

- Individuals below 135% of the poverty level ($13,055 single / $17,619 couple)[1] with assets no more than $6,000 per individual and $9,000 per couple (indexed to inflation):
  - no deductible and no monthly premium
  - no gap in coverage
  - up to a $2 copay for generic drugs and up to a $5 copay for brand name drugs (copays are indexed for inflation)
  - $0 copay for all prescriptions once the out-of-pocket limit is reached

[1]Estimated poverty guidelines for 2006 for single and double families based on assumed price inflation using most recent CBO forecast and projections (May 20, 2003).

- **S** authority for states to provide coverage for over-the-counter drugs through their Medicaid programs

- Individuals below 150% of the poverty level ($14,505 single / $19,577 couple) with assets no more than $10,000 per single and $20,000 per couple (indexed to inflation):
  - **S** $50 deductible
  - **S** sliding scale premium
  - **S** no gap in coverage
  - **S** 15% coinsurance for drug spending up to the catastrophic limit
  - **S** 2.5% coinsurance for drug spending above the catastrophic limit

Under the 2006 drug delivery model, insurers would bear partial risk for drug spending, which would be moderated through reinsurance and risk corridors. In the first two years of the drug benefit, insurers would bear a smaller portion of risk for total drug spending because of the risk corridors. Beneficiaries would have the choice of two plans in a given area. If such plans fail to materialize, then the federal government would annually contract with an entity to provide Part D coverage, commonly referred to as a fallback plan. The fallback plan would bear performance risk only. Standard coverage and national premium levels, adjusted for differences in drug utilization, would apply.

Those beneficiaries who receive drug coverage through their employer have the option to decline the new Medicare Part D drug benefit and remain in their current plan. Should an employer decide to end such coverage, beneficiaries may enroll in the new program without any late enrollment penalty. Moreover, those employers providing coverage that is of equal value to the Medicare benefit would be eligible for a new 28-percent federal subsidy for any drug costs between $250 and $5,000.

Title II - Medicare Advantage

Beginning in 2006, beneficiaries would have the option to enroll in a new program, referred to as "Medicare Advantage." The Medicare Advantage (MA) program would provide a choice of coordinated care health plans, eventually replacing the current Medicare + Choice program. These plans would include local health maintenance organizations or regional and local preferred provider organizations.[2] To help jump-start participation in the MA program, payment rates would increase during 2004 and 2005 by indexing them to current Medicare fee-for-service rates.

Under the MA program, all health plans would be required to offer at least a standard drug benefit. Also, they would be required to offer a benefit package that is equivalent to Medicare Parts A and B. In

[2]PPOs essentially are a "hybrid" between fee-for-service plans whereby insurance companies pay the fees set by hospitals and doctors, and HMOs which manage patient care through contracts with certain providers willing to accept negotiated payment rates. PPOs contract with providers, but usually the number of participating providers is greater than most comparable HMO networks. PPOs also have more generous out-of-network benefits compared to HMOs.

addition, plans would be required to provide catastrophic benefits for traditional medical care, and they would be encouraged to offer disease management, chronic care, and quality improvement programs to their enrollees.

To help ensure participation in rural and urban areas equally, the Conference Report includes several provisions ranging from bid structure to network adequacy. First, PPOs could submit bids on a regional basis. The Secretary could create between 10 and 50 regions. To the extent possible, the Secretary would include multi-state metropolitan statistical areas in a single region, except where necessary to establish a region of such size and geography needed to maximize PPO participation. PPOs that cover a region would have to offer a single deductible and protection against high out-of-pocket expenses.

S.1 originally restricted the number of PPO bids per region to three. However, the conference report changed this provision to allow for multiple bids. Such bids would reflect the cost of coverage for required benefits, including assumptions about the number and health of possible enrollees. Payments to the regional PPO plans then would be calculated using a benchmark amount. The benchmark amount is a combination of plan bids and a statutory payment rate, connected to fee-for-service Medicare. Plan bids that are equal to or exceed the benchmark would be paid the benchmark rate. Bids below the benchmark would receive the bid amount. In addition, the difference between the bid and the benchmark would be split 75 percent for the beneficiary to help reduce their premiums. The remaining 25 percent would be returned to the federal government. The federal government would share the risk with insurance companies and PPOs for any potential profits and/or losses through the use of risk corridors for the first two years.

Second, the Conference Report includes an additional section for plan entry and stabilization. For instance, the Secretary has discretion to access a $10 billion fund for the purpose of enhancing payments for plans in regions where such plans are nonexistent. In addition, a 3-percent bonus payment is made available for health plans that bid on a national basis for one year. And lastly, $25 million is authorized annually for health plans to utilize as an incentive to contract with essential hospitals. Collectively, the funding will help attract and retain private health plan options for rural and urban beneficiaries.

Unlike S. 1, the legislation includes a demonstration that puts the traditional Medicare fee-for-service program in direct competition with the private health plans sector. This demonstration also is referred to as premium support or comparative cost adjuster. Starting in 2010, the Secretary would have discretion to select six metropolitan statistical areas that have two local private plans present in the area and that demonstrate at least 25 percent total local penetration. The demonstration would be phased-in over four years and sunset in 2016. Part B premiums for beneficiaries remaining in the traditional Medicare program could not increase or decrease by more than 5 percent in any year as a result of the test. In addition, beneficiaries with incomes below 150 percent of the poverty level, with assets described earlier, would be protected from any increase in premium rates. Payment rates for plans selected in these areas, including traditional Medicare, would reflect changes for the demographics and health risks of enrollees. If the Medicare program disproportionately enrolls beneficiaries with higher medical costs, then beneficiary premiums would be adjusted to compensate for such cost increases.

Title III - Combating Waste, Fraud, and Abuse

The Conference Report includes a provision regarding payments for durable medical equipment and certain orthotic items. The payment policy is a combination of both House and Senate proposals. S. 1 proposed a seven-year freeze at CPI for such products. The House's original proposal imposed competitive bidding beginning in 2004. The Conference agreement freezes payments for 2004-2008. It then reduces payment rates in 2005 for wheelchairs, hospital beds, air mattresses, nebulizers, diabetic supplies, and oxygen. The rate is adjusted to reflect the prices paid under the Federal Employee Health Benefit Program. Starting in 2007, the Secretary shall select 10 of the largest metropolitan statistical areas for competitive bidding. In 2009, the Secretary shall expand this competitive bidding authority to 80 MSAs, and further expand for years thereafter. During this period, the Secretary is authorized to exclude certain noncompetitive areas, such as rural states or regions, from competitive bidding altogether.

In addition, the Conference Report reforms payment rates for outpatient drugs and biologicals. Similar to S.1, payments would be 85 percent of the April 1, 2003 average wholesale price (AWP). However, the legislation adds an exception to this policy for 28 drugs where the Secretary's proposed rule indicated, on the basis of General Accounting Office and HHS Inspector General studies, that the market price was a different percent of AWP. No payment would be lower than 80 percent of AWP. Manufacturers could submit data to the Secretary for a different (higher) price of AWP.

Beginning in 2005, physicians would be paid 6 percent above the average sales price (ASP), also referred to as ASP + 6. The following year, physicians would have a choice of being paid at the ASP + 6 rate or having drugs furnished to them by competitively selected contractors.

Meanwhile, the Conference Report includes a work component (level 1 office visit) in the payment methodology for time spent administering such drugs. It also increases payments for oncology nurses by using new survey data. This survey data instrument was included as part of S. 1.

Title IV - Rural Provisions

The Conference Report contains several Medicare Part A and Part B rural payment provisions. The list reflects provider measures:

- Full and permanent equalization of the standardized payment amount for small and rural hospitals, effective April 1, 2004 (similar to S.1).

- Increased Medicare Disproportionate Share Hospital (DSH) payment caps up to 12% for rural hospitals, effective April 1, 2004 (similar to S.1).

- Additional bonus payment up to 25% for small, low-volume hospitals with less than 800 total discharges, effective October 1, 2004 (similar to S.1).

- Lowered hospital labor share index from 71% to 62%, effective October 1, 2004 (similar to S.1).
- A 2-year extension of hold-harmless payments for rural hospitals receiving Medicare outpatient prospective payments (similar to S. 1).

- Critical Access Hospital (CAH) improvements and other changes.
  - **S** Increased payments of 101% of costs (similar to House proposal)
  - **S** Flexibility of bed-size limit up to 25 (similar to S.1)
  - **S** Coverage for emergency on-call providers (similar to S.1)
  - **S** Reinstatement of periodic interim payments (similar to S. 1)
  - **S** Inclusion of psychiatric and rehabilitation distinct part unit beds paid at respective prospective payment system rate (new provision)
  - **S** Additional grant funding for 4 years, increased from $25 million to $35 million annually (similar to S. 1)

- A 5% bonus payment for rural home health suppliers (similar to S. 1).

- Revised ambulance payments based on the regional floor and the adjustment for low- population rural areas. In addition, payments will increase by 1% across-the-board for services furnished in urban areas and 2% for services furnished in rural areas. Medical necessity for certain air ambulance services also is included (combination of House and Senate proposals).

- Exclusion of certain services furnished by rural health clinics and federally qualified health centers from skilled nursing facility consolidated billing requirements (similar to S.1).

- A 5% bonus payment for physicians practicing in designated scarcity areas, effective 2005-2008 (similar to House proposal).

- Established floor of 1.0 for the work geographic index used to compute fee-schedule amounts for rural physicians.

- Redistribution of unused residency positions from hospitals that have not met their residency caps. Rural facilities are given priority for redistributed residency slots.

Title V - Provisions Relating to Part A

Additionally, the Conference Report contains the following major Medicare payment policies for hospitals unrelated to geographic location:

- A full market basket update, also referred to as a full inflationary update, for years 2005-2007, provided such facilities submit quality reporting data as currently supplied under the National Voluntary Hospital Reporting Initiative. Those facilities that choose not to submit such measurements will receive a payment decrease of market basket minus .4% for each year that data is not submitted during this period (new provision).

- Revised indirect medical education (IME) payments to hospitals for the purpose of training medical residents. Payment adjustments would increase from 5.5% (current law) to 6.0% starting April 1, 2004. Adjustments would then be revised to 5.8% for FY05, 5.55% for FY06, 5.35% for FY07, and then return to 5.50% for FY08 and thereafter (S. 1 included an adjustment of .03% for 2004).

- An 18-month moratorium on new speciality hospital construction that relies on physician investment and self-referral, effective on the date of enactment of the Medicare bill. Exemptions are included for hospitals in existence prior to November 18, 2003. The legislation stipulates such grandfathered facilities can expand no greater than 50% of their current physical structure or 5 additional beds. Such facilities also cannot alter their speciality to include additional functions. Lastly, the hospitals cannot expand the number of current physician investors/owners. During this moratorium period, the Medicare Payment Advisory Commission, in consultation with the General Accounting Office and HHS, must study the effects of the hospital exemption for physician ownership in specialty hospitals within 15 months from date of enactment of the bill.

- New inpatient technology payments for hospitals.

Title VI - Provisions Relating to Part B

The following is a list of major provisions related to physicians, other Part B providers, and beneficiaries:

- Increased annual physician payment adjustments of 1.5% for FY2004-2005. Current law requires that physician fees be cut by 4.5% for FY2004. The Conference Report reverses that policy and maintains the new adjustment for 2 years (House proposal).

- Inclusion of podiatrists, dentists, and optometrists under private-contracting authority.

- A 5-year freeze for clinical laboratory services at current payment rates for 2004-2008.

- A 2-year moratorium on therapy caps.

- Initial physical examinations available to all newly enrolled Medicare beneficiaries starting in 2005. Beneficiaries also will be covered for cardiovascular screening blood tests and diabetes screening tests for at-risk individuals.

- Beginning in 2005, the annual Medicare Part B deductible will increase from $100 to $110, and indexed to growth for Part B expenditures each year thereafter.

Title VII - Provisions Relating to Parts A and B

The following is a list of major provisions related to home health and other Part A and B services:

- Annual home health payments at market basket minus .8% for 2004-2006. Continue current outlier policy, allocating no more than 3% for outlier payments.

- Improvements in the national local coverage determination process for purposes of medical technology changes.

- Requirement that Medicare Advantage plans meet quality reporting requirements.

Title VIII - Cost Containment

The Conference Report contains a new cost-containment mechanism to provide transparency in accounting and Congressional review of the Medicare program if general revenue contributions exceed 45 percent of program spending.

In addition, the legislation begins applying income-testing to Medicare Part B premiums for beneficiaries starting in 2007. It includes:

- All beneficiaries with incomes below $80,000 (single) and $100,000 (couple) will see no change in their premium amount and continue to receive a 75% subsidy of such premiums by the federal government under current law.

- Beneficiaries with incomes between $80,000 and $100,00 (single) and $160,000 and $200,000 (couple) will receive a 65% subsidy and be required to pay 35% of the monthly premium.

- Beneficiaries with incomes between $100,000 and $150,000 (couple) and $200,000 and $300,000 (couple) will receive a 50% subsidy and pay 50% of the premium.

- Beneficiaries with incomes between $150,000 and $200,000 (single) and $300,000 and $400,000 (couple) will receive a 35% subsidy and pay 65% of the premium.

- Beneficiaries with incomes above $200,000 (single) and $400,000 (couple) will receive a 20% subsidy and pay 80% of the premium.

Title IX - Administrative Improvements, Regulatory Reduction, and Contracting Reform

The Conference Report establishes a center with the Centers for Medicare and Medicaid Services (CMS) to administer Parts C and D of the Medicare program. The new center would be responsible for providing notice and information to beneficiaries and shall be established no later than January 1, 2008.

The Conference Report also includes two funding measures for increased and improved provider and beneficiary education. The legislation authorizes such sums as may be necessary for years FY 2005 and thereafter for the purpose of billing, coding, and other appropriate items affecting providers as determined by the Secretary. In addition, the legislation establishes a Medicare Beneficiary Ombudsman office, which is required to work with State Health Insurance Counseling programs. The legislation also makes program improvements to the toll-free number 1-800-Medicare for beneficiary questions.

The Conference Report creates a new process for providers that have been overpaid by the Medicare program. In cases where overpayment within the standard 30 days is determined to be a hardship, the Secretary is required to enter into an extended repayment plan of at least 6 months but no longer than 3 years (or 5 years if *extreme* hardship is demonstrated). The legislation also requires the Secretary to establish a process so providers and suppliers can correct minor errors in claims that are submitted for payment with 1 year after enactment of the bill.

Title X - Medicaid and Miscellaneous Provisions

The Conference Report establishes a temporary increase in state Medicaid disproportionate share hospital (DSH) allotments. Currently, hospitals serving a large number of uninsured patients and Medicaid recipients receive additional DSH payments to help defray the cost of uncompensated care. The legislation includes two changes concerning such payments:

- Allotments for FY 2004 are to increase by 16%, effective upon enactment of bill; and
- Allotments for FYs 2004-2008 are to increase by 16% for those states defined as "low DSH" states under current law.

The Conference Report modifies the definition of Medicaid "best price" practices to allow certain public safety net hospitals to negotiate inpatient drug prices.

The measure also provides partial payments to hospitals, physicians, and ambulance providers for the uncompensated care of undocumented aliens as mandated by the Emergency Medical Treatment and Labor Act (EMTALA). The Balanced Budget Act of 1997 originally provided $25 million per year to states for such expenses. The Conference Report increases this funding to $250 million per year for FY2005-FY2008. This money would be available to providers in all states, with an emphasis on those states with the highest number of undocumented alien apprehensions. It ensures providers are reimbursed directly through an application process developed by the Department of Health and Human Services for actual services rendered. It is not a new benefit for individuals.

Title XI - Access to Affordable Pharmaceuticals

Similar to S. 1, the Conference Report includes provisions aimed at providing greater access to generic name drugs. Specifically, the legislation provides only one 30-month stay for patent infringement suits involving a generic drug application. The legislation also refines and clarifies existing incentives for generic manufacturers for the first 180 days with market exclusivity.

In addition, the Conference Report closely follows the provisions established under S. 1 concerning the importation of pharmaceuticals. The legislation provides authority to the Secretary of Health and Human Services to create a system for the importation of drugs from Canada by pharmacists, wholesalers, and individuals, but only if the Secretary first certifies the safety and cost-savings of drugs imported from Canada.

Moreover, the legislation includes a new provision requiring the Secretary to conduct a study on the safety and efficacy concerns associated with the importation of drugs from foreign countries. The study is due within 12 months of the date of enactment of the bill. Additionally, the Secretary of Commerce, the International Trade Commission, the Secretary of HHS, and the United States Trade Representative must complete a study within 9 months of the date of enactment that examines the impact of pharmaceutical price controls (and related practices) in countries that are members of the Organization of Economic Cooperation and Development. Further, the Conference Report calls on the Secretaries of Commerce and HHS, and the USTR to develop a strategy that addresses the problem of pharmaceutical price controls (and related practices) through negotiations and to provide an interim report on that strategy (particularly as it relates to

the United States-Australia Free Trade Agreement negotiations) to the appropriate committees of Congress within 90 days of enactment.

Title XII - Tax Incentives for Health and Retirement Security

The Conference Report includes several modifications to the taxation and benefit structure of medical savings accounts. First, the legislation renames these accounts to Health Savings Accounts (HSAs). Such accounts now will be available to all individuals – not just employees of small businesses and the self-employed. Second, contributions by an employer are not included as taxable income. Contributions by an individual also will be tax deductible. Total yearly contributions can be as large as the individual's health insurance plan deductible, between $1,000 and $5,000 for self-coverage and $2,000 and $10,000 for family coverage.

Interest and investment earnings generated by the account are not taxable within the HSA. Any distributions from the account will not be taxed as long as the money is used for qualified medical expenses including, but not limited to, prescription and over-the-counter drugs, long-term care services, and health-coverage purchases continued under COBRA policies. The new HSA provision is effective for taxable years beginning after December 31, 2003.

COST

As of November 20, the Congressional Budget Office (CBO) estimated that the legislation would increase direct spending by $395 billion over the 2004-2013 period, based on preliminary review. It also would lead to an increase in federal revenues totaling $500 million over the same 10-year period.